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## Disruptive Innovation by Genetic Modification Technology as a Market Driver to Target Unmet Vaccine Needs

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## Summary

In essence, this dissertation evaluates the disruptive innovation that has been started in the vaccine market by the introduction of GM technology with the purpose of targeting unmet vaccine needs. The studies aim to identify challenges that novel technologies have to meet to reach for successful market implementation. Main implementation barriers, together with their different underlying causes, are identified and evaluated from three different perspectives; regulatory, industry, and academia. The five research chapters (*chapters 2 to 6*) present new findings describing and evaluating the dynamics of these innovation barriers for successful market implementation. Where *chapters 2* and *5* evaluate the dynamics relating to market potential of GM vaccines from a multidisciplinary perspective, distinguishing between critical success factors (*chapter 2*) and market implementation potential (*chapter 5*), *chapters 3* and *4* present a more in-depth look at the current and future prospects of the global GM vaccine market (*chapter 3*) and the current state-of-the-art and newly generated vector-based technologies (*chapter 4*). *Chapter 6* gives a KOL's perspective on the strengths, weaknesses, opportunities, and threats that are essential in order to define determining factors for strategy-oriented-planning and decision-making-processes in the future.

The eight chapters show that GM technology offers new technical opportunities for vaccine development against previously untargeted diseases. Simultaneously, novel technologies provide extensive opportunities at different levels where the current technologies fail or are insufficient to fulfill the task. Furthermore, the studies evaluate the existing valley of death between clinical phases and market introduction of GM vaccines. The primary reason for this occurrence is identified to be the complex and additional rules and regulations required for the authorization of these vaccines. Noteworthy, the high societal, commercial, and public health value offered by innovative technologies implies an increased market transition demand in the regulatory landscape with respect to novel GM vaccines. Subsequently, on the basis of this premise, other barriers within the context of successful market implementation of GM vaccines will gradually be overcome in order to target unmet vaccine needs for the benefit of public health.

In essence, the key element and, simultaneously, one of the most challenging hurdles turns out to be the crucial collaboration between different stakeholders, with their different perspectives working with different paradigms offering different insights resulting in beneficial decision-making and accomplishing consensus when interactive complexity plays a predominant role. Various stakeholders at different levels must understand each other's perspective and come to the realization that only jointly they can anticipate market implementation barriers in a collaborative manner that will eventually lead to a strategic dialogue. Consequently this will be leading to an increased chance of reaching a consensus, an enormous contribution to public health, and economical benefits for

each and every stakeholder involved. The three relevant disciplines involved in the studies of this dissertation are in one way or another interdependent and have to interact and interrelate to achieve the common goal of vaccine availability from bench to bed. In essence, such outcomes are desirable with the purpose of increased novel vaccine development that will, without a shadow of doubt, be realized in the near future.